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BY ECF & FEDERAL EXPRESS

Hon. Esther Salas, U.S.D.J.
United States District Court for the District of New Jersey
Martin Luther King, Jr. Federal Building and U.S. Courthouse
50 Walnut Street
Newark, NJ 07101

Re: *Mylan Pharmaceuticals, Inc. v. Celgene Corporation*
Civil Action No. 14-2094 (ES) (MAH)

Dear Judge Salas:

Our firm, along with Wilson Sonsini Goodrich & Rosati, represents plaintiff Mylan Pharmaceuticals Inc. ("Mylan") in the above matter. Presently pending before Your Honor is Defendant Celgene Corporation's Motion to Dismiss, relating to which the Court held oral argument on December 9, 2014.

We write to Your Honor with respect to a recent decision by Judge Robert W. Sweet in the Southern District of New York in *The People of The State of New York v. Actavis, PLC and Forest Laboratories, LLC,* Civil Action No. 14-7473 ("*Namenda*"). That decision provides critical additional support for, and is directly relevant to, Mylan's position on the issues of (1) concerted action and conspiracy law, including the separateness of the relevant economic actors, (2) the question of defining a single-brand product market, and (3) the pretextual nature of Defendant's claimed procompetitive business justifications. We respectfully request that the Court consider this new decision and the following comments in connection with the pending motion.

Namenda involves a strategy by a branded firm to impede generic competition to the detriment of consumers. Specifically, New York's Complaint alleged that the *Namenda* Defendants have engaged in "product hopping," an anticompetitive scheme to switch an immediate release tablet version of Namenda (which faces imminent generic competition) with

an extended release capsule version of Namenda (which does not face any prospect of imminent generic competition).

The *Namenda* Court last Thursday granted New York's motion for a preliminary injunction and ordered that Actavis and Forest ("*Namenda* Defendants") be enjoined from discontinuing the availability of the previous immediate release tablet form of Namenda until resolution of the litigation. *See id*. Dkt. No. 80 (Dec. 11, 2014) (redacted public version of opinion) (copy attached).

Judge Sweet's opinion is precisely relevant here for several reasons. First, in applying the standard for a preliminary injunction, the *Namenda* court found that New York demonstrated a substantial question as to the legality of the defendants' vertical agreement with their drug distributor under Section 1 of the Sherman Act. *Namenda* Dkt. No. 80 at 122-26. Citing the Supreme Court's opinion in *American Needle, Inc. v. National Football League*, 560 U.S. 183, 195 (2010), the court noted that "[c]oncerted action within the meaning of Section 1 exists when an agreement between 'separate economic actors pursuing separate economic interests . . . deprives the marketplace of independent centers of decisionmaking.'" *Id.* at 123. Because the *Namenda* Defendants and their drug distributor—an "independent contractor"—were "separate economic actors, occupying different roles in the [drug] supply chain," the court found that concerted action was established. *Id.* at 123-24.

Similarly, in this case, Mylan alleges that Celgene and the wholesalers and distributors with which Celgene has entered into written agreements governing the sale of Thalomid and Revlimid products under the REMS programs are separate economic actors occupying different roles in the vertical supply chain. Compl. at ¶¶ 6, 72, 194-95, 213-14, 262, 275, 289, 353, 361, 369; *see also* FTC Amicus, Dkt. 26, at 17-19.

Second, the *Namenda* court found that the product market in that case was limited to a single brand-name drug and its generic equivalents (the "memantine market"), noting that other courts have found the same in circumstances "where the challenged conduct involves a branded drug manufacturer's effort to exclude generic competition." *Namenda* Dkt. No. 80 at 104. Among other things, the court noted that defendants' own business strategy—to exclude AB-rated generic competition to protect their monopoly profits—demonstrated that the relevant market should consist of the brand-name drug and its generic equivalents only. *Id.* at 45-47.

Third, the *Namenda* court—on a full evidentiary record—concluded that defendants' procompetitive business justifications were "pretextual." *Namenda* Dkt. No. 80 at 118. The court found that defendants' "later-in-time" rationalizations for their strategy to exclude generic competition were not persuasive, as they were not quantified and were unsupported by defendants' contemporaneous business documents. *Id.* at 70-75, 119-120 (citing defendants' statements that the purpose of their switch from Namenda IR to Namenda XR was to avoid

generic competition, not the host of other reasons defendants sought to justify their conduct in litigation).

Here, Mylan—throughout its complaint—alleged that Celgene's purported "safety" or "products liability" concerns are false. Compl. at ¶¶ 158, 192, 196, 211, 215, 233, 250, 264, 277, 292. The real reason that Celgene refuses to sell samples to Mylan—despite the fact that Mylan has FDA-approved safety protocols and offered to indemnify Celgene—is that Celgene does not want to lose the monopoly profits its earns by charging consumers hundreds of dollars per dose for Thalomid and Revlimid; profits which it can maintain only through the continued exclusion of cheaper generic competition. Compl. at ¶¶ 10, 158, 192, 196, 211, 215.

We thank the Court for its consideration of this matter.

Respectfully submitted,

Arnold B. Calmann

ABC/jbh
Enclosure

cc: Counsel of record (by ECF & email)